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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/695,347 | 10/28/2003 | Shun-Por Li | MCP-5007 | 5595 |
| 27777 | 7590 | 11/26/2007 | | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER WEBMAN, EDWARD J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/26/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|--|--|--|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p align="center">10/695,347</p> | <p>Applicant(s)</p> <p align="center">LI ET AL.</p> | |
| | <p>Examiner</p> <p align="center">Edward J. Webman</p> | <p>Art Unit</p> <p align="center">1616</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 17-23 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-23 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 17-23, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al in view of Chang et al and Raiden et al.

Joshi et al teach beadlets comprising an active and a binder (abstract). 3-70 % binder, including the hydrocolloid hydroxypropylmethyl cellulose with a viscosity of 2-200 cp, is disclosed (column 9 line 66-column 10 line 22). Other hydrocolloids, including carrageenan, may be employed (column 10 lines 23-30). Lubricants are disclosed (column 5 lines 41).

Chang et al teach partially deacylated gellan gum which forms elastic gels having low brittleness (abstract).

It would have been obvious to one of ordinary skill to add a partially deacylated gellan gum to the beadlet of Joshi et al to achieve the beneficial effect of modifying its flexibility in view of Chang et al.

As to the percent range and viscosity of hydroxypropylmethylcellulose, Joshi et al teach a range which overlaps those claimed. As to the claimed cloud point range, it is argued that the polymer of Joshi et al inherently possesses such a range, because it is the same polymer as that claimed. As to the claimed ranges of the other ingredients, optimum suitable amounts may be obtained by routine experimentation, absent a showing that they are essential or provide an unexpected result. In re Boesch 205

USPQ 215 (CCPA 1980). As to the particular claimed lubricant, glyceryl monostearate, Raiden et al teach that it is well known in the art as such (column 5, lines 3-10). Thus, it would have been further obvious to add glyceryl monostearate to the composition of Joshi et al for its beneficial effect as a lubricant in view of Raiden et al.

As to the claimed shell, it is argued that if the shell comprises the same composition as the core, they become indistinguishable. As to the claimed shell portion and core portion, "portion" includes 100 %. As to the claimed burst release, such is merely an intended use. As to the claimed substantial freedom from pores of the claimed range, Joshi et al do not disclose pores of any size.

Applicants argue that Joshi et al concern hard spheres whereas Chang et al concern liquids and gels. However, applicants do not cite where in Joshi et al "hard spheres" are disclosed. Further, as noted above, Joshi et al disclose hydrocolloids such as carrageenan. Additionally, a wet mass is needed for efficient extrusion (abstract). Even if the Joshi et al beads fit the characterization of "hard", making such beads less brittle by adding a deacylated gellan gum would be seen, even by the layman, as advantageous to, for example, shelf-life.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PATENT EXAMINER
GROUP 1616